EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** ***Cheryl Berden, et. al. v. Ethicon, Inc.*** **Case No. 2:14-cv-21966**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

SUPPLEMENTAL REPORT OF DR. VLADIMIR IAKOVLEV FOR ISSUES RELATED TO MERSILENE MESH

I. General Issues of Mesh Erosion/Exposure through Skin or Mucosa

Mesh exposures can be separated into two groups: primary and secondary. Primary exposure occurs at a never healed operative wound, while secondary erosion occurs either through a healed scar or through initially unaffected tissues. The secondary type of erosion can occur sometimes months and years after mesh implantation.

For the primary type, exposure through a never healed operative wound is either caused or complicated by the presence of a foreign object in the wound. Although it can be partially dependent on surgical technique, the mesh itself is a major factor in the early mesh exposures. Presence of a foreign body in a wound is a known cause for retarded healing. [1] The foreign object acts as a physical barrier in the wound. Also, multiple other factors such as interrupted blood

supply that cannot be restored quickly through the mesh, foreign body type inflammation, bacterial retention by the foreign body and superimposed acute inflammation slow healing.

In relation to the secondary type of erosions, or extrusion through healed or unaffected skin or mucosa, published literature indicated that mesh specific factors play a role. [2] [3] Solid silicon strips or silicon coated meshes had higher rates of erosion pointing to material specific properties. [4] [5] [6] Microporous material with low tissue adherence, such as expanded polytetrafluoroethylene (ePTFE) also showed a high exposure rate. [7] Comparatively, meshes made out of the same material, polypropylene, but with a different pore size showed an advantage of the larger pore designs. [2] In addition to the lower tissue adherence, meshes with smaller pores do not allow tissue ingrowth and likely interfere with the vascularisation and innervation of the overlying mucosa. As with all flap surgeries, insufficient neurovascular supply can lead to dystrophic (atrophic) changes and necrosis of a thin flap dependent on a limited lateral supply. For example, animal models showed that the rate of erosion was dependent on mesh size. Larger mesh implants had a higher risk of exposure. [8] [9]

Overall, the published literature and cumulative clinical experience demonstrated that the risks of mucosal erosion are dependent on the design. [3] [10] [11] [12] [13] The objects become exposed because they do not become an integral and physiological tissue component, but rather remain a foreign body that can damage the tissues, interrupt healing, and is targeted for destruction, encapsulation and expelling. [14] [15] [16] [17] [18] [19] The degree of these negative effects is dependent on an overall device design and it may take many months, years or even decades before the negative effects become clinically apparent.

II. General Issues of Infection and Specifics of Mersilene Mesh

As for any foreign object, infection can be either introduced with the mesh during implantation, or the device can become seeded later. A secondary contamination can occur either through the wound of mesh erosion (skin or mucosa), or hematogeneously, through blood stream from a distant site such as a distant wound. There can also be a combination of sources that would have a compounding effect. In either scenario, surface and spaces within the mesh structure provide opportunities for bacterial adhesion and shelter. Therefore, characteristics of a material and the overall design of a device are the most important modifiable factors effecting the risk of infection.

Presence of bacteria on the implant can be dormant for a long time. It has been shown that adhered bacteria can be seen in up to a third of explanted meshes. [20] However, in many cases presence of infection is subclinical. Bacteria have been detected on meshes explanted for reasons other than a clinically apparent infection. Several studies indicated that there is a delay of several months or years before the infection can manifest clinically. [21] [22] [23] [24] [25] [26] [27] Therefore, length of either experimental or clinical studies is important to accurately assess the risks of infection for a particular mesh design.

Historically, it has been noted during the early search for better mesh materials that constructs with smaller spaces in the mesh structure are more prone to retain infection. Smaller spaces also limit tissue ingrowth through the mesh. Multifilament sutures, in comparison to monofilament ones, were known to be prone to infection for several decades. [28] The earlier reports of infections associated with multifilament mesh (Mersilene) date back to at least 1970s. [29] Also in 1970s an experimental study showed that immobile bacteria can propagate inside

multifilament materials. The spreading was correlated to the capillary properties of the threads. [30] These experimental results comparing suture materials were further supported by other studies in the 1980s. [31] [32] [33] Later studies indicated that microporous, multifilament and composite meshes contain spaces with limited access for the immune cells, and therefore introduced higher risks for bacterial retention and spread. [34] [35] [36] [37] Multifilament meshes also have a larger surface area compared to monofilament designs. [26] Accordingly, in experimental settings, there was a trend for higher volumes of bacteria adherent to multifilament mesh. [26] [38]

By the 1990s the volume of meshes used for hernia repair provided sufficient data to draw long term conclusions. For example, a study concluded: "multifilament polyester mesh had a significantly higher mean number of complications per patient (4.7 vs 1.4-2.3; P<.002), a higher incidence of fistula formation (16% vs 0%-2%; P<.001), a greater number of infections (16% vs 0%-6%; P<.05), and more recurrent hernias (34% vs 10%-14%; P<.05) than the other materials used." [27]

One of the key parameters in mesh design is to allow a free traffic of the immune cells - neutrophils. These cells are recruited by the body to fight bacterial infections. [1] This knowledge was transferred to mesh designs and classifications. [39] [40] [41] [42] [34] Larger spaces within mesh (larger porosity) allow tissue ingrowth and free traffic of immune cells, while smaller spaces restrict both physiological functions. Mesh constructs with larger spaces throughout the entire mesh were classified as type I; those with only small spaces were grouped as class II; and more complex constructs with a range of spaces (mixed micro-and microporous) were designated as class III:

Type I: Totally macroporous prostheses, such as Atrium, Marlex, Prolene and Trelex. These prostheses contain pores larger than 75 microns, which is the required pore size for admission of macrophages, fibroblasts (fibroplasia), blood vessels (angiogenesis) and collagen fibers into the pores [Bobyn et al. 1982, White 1988, White et al. 1981].

Type II: Totally microporous prostheses, such as expanded PTFE (Gore-Tex), Surgical Membrane, and Dualmesh. These prostheses contain pores that are less than 10 microns in at least one of their three dimensions.

Type III: Macroporous prosthesis with multifilamentous or microporous components, such as PTFE mesh (Teflon), braided Dacron mesh (Mersilene), braided polypropylene mesh (Surgipro) and perforated PTFE patch (MycroMesh).

Type IV: Biomaterials with submicronic pore size, such as silastic, Cellgard (polypropylene sheeting), Preclude Pericardial membrane and Preclude Durasubstitute. These are not suitable prostheses for hernia repair; however, in combination with Type I biomaterials, they can provide adhesion-free composites for intraperitoneal implantation [Amid et al

[34]

Multifilament meshes are a typical class III design since they have larger pores in the knit pattern, but are knitted using multifilament thread that contains smaller spaces between the filaments in the thread. The smaller spaces are a critical component for the risk of infection:

Infection

Surgical infection promoted by implantation of biomaterials, such as sutures and prostheses, is caused by infiltration and proliferation of bacteria into and within the pores and interstices of these synthetic materials. When interstices or pores are less than 10 microns, in each of their three dimensions, bacteria averaging 1 micron cannot be eliminated by macrophages and neutrophilic granulocytes, which are too large to enter a 10 microns three-dimensional pore [Alexander et al. 1967, Elek and Conen 1957, Neel 1983]. Braided sutures [Elek and Conen 1957] and prosthetic material [Neel 1983] with interstices and pores less than 10 microns provide a suitable housing for bacteria and development of infection by admitting bacteria but excluding macrophages. By admitting both macrophages and bacteria, biomaterials with pores larger than 10 microns create a major challenge for the proliferation of bacteria, and thus do not contribute to the development of surgical infection [Larson and Harrower 1978, Law and Ellis 1991, Martin et al. 1982, Usher et al. 1959].

Type II and III prostheses are similar to braided suture materials, and by harboring bacteria can promote their growth, likewise resulting in biomaterial-related infection [Alexander et al. 1967, Elek and Conen 1957]. Figure 1 is an example of an infected and partially extruded Type II prosthesis; Figure 2a and b, of an infected Type III.

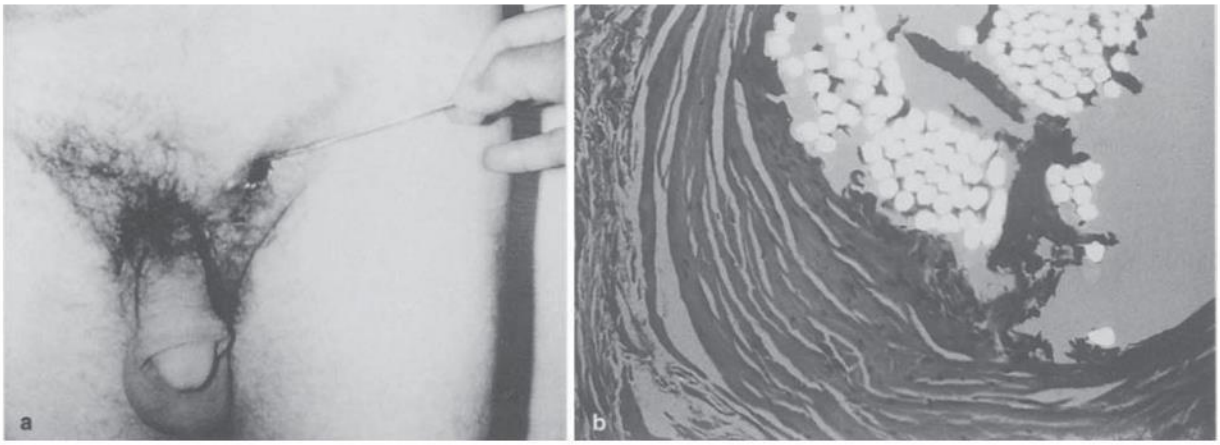


Fig. 2a, b
a Chronic infection and sinus tract formation after hernia repair with Surgipro. **b** Multifilamentous fibers of Surgipro surrounded by inflammatory cells (polarized lighting)

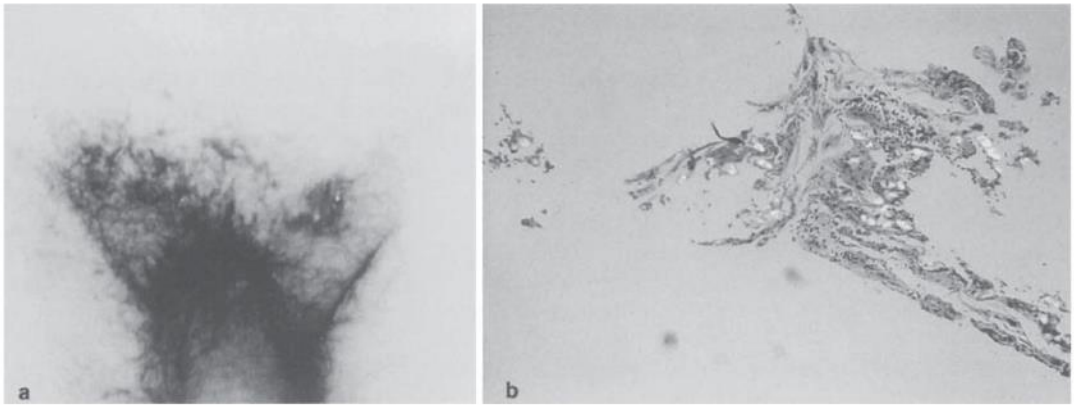


Fig. 3a, b
a Chronic infection and sinus tract formation after hernia repair with Marlex mesh, sutured in place with braided suture material. **b** Braided suture material surrounded by inflammatory cells (polarized lighting)

[34]

Mersilene mesh is a class III complex mesh that combines both macro- and microporous structures:

TABLE 1 The classification of synthetic biomaterials; adapted from Karlovsky et al. *[4]*

Synthetic material (manufacturer)	Filamentous structure	Mesh type	Pore size
Polypropylene, Marlex (CR Bard, Covington GA)	Monofilament	I	Macro
Polypropylene, Prolene (Ethicon, Somerville NJ)	Monofilament	I	Macro
Polypropylene, Atrium (Atrium Medical, Hudson NH)	Monofilament	I	Macro
Polypropylene, TVT (Johnson and Johnson, New Brunswick NJ)	Monofilament	I	Macro
Polypropylene, SPARC (American Medical Systems)	Monofilament	I	Macro
Polypropylene, Lynx (Boston Scientific, Natick, MA)	Monofilament	I	Macro
Polypropylene, T-Sling (Caldera Medical, Augura Hills, CA)	Monofilament	I	Macro
PTFE (Teflon, CR Bard)	Multifilament	III	Micro
Expanded PTFE, Gore-Tex (W.L. Gore, Flagstaff AZ)	Multifilament	II	Micro
Polyethylene tetraphthalate, Mersilene (Ethicon)	Multifilament	III	Macro/micro
Polyester-silicone coated, Intemesh (American Medical Systems)	Multifilament	IV	Submicro
Polyglycolic acid, Dexon (Davis and Geck, Danbury CT)	Multifilament	Absorbable	Macro
Polyglactin 910, Vicryl (Ethicon)	Multifilament	Absorbable	Macro

[43]

The earliest attempts to use multifilament mesh (Mersilene) for pelvic surgeries were in the 1960s. [44] Among other results the publications reported suprapubic abscess and chronic sinus formation. Later, erosions, infection and formation of chronic sinus were reported in 1990s for Mersilene mesh used for pelvic prolapse surgeries. [45] [46] A publication stated: "This procedure is not recommended as a primary procedure for the repair of the anterior vaginal segment. It is reserved for patients who have had two or more reparative failures." [46] More data were accumulated by 2000. A larger study followed 273 patients who underwent colpopexy using Mersilene mesh. They reported an overall erosion rate of 5.5%. [47] The study did not aim to detect the life-long risk of mesh erosion, but rather focused on comparison of different surgical approaches. Since for the most groups the median follow up time was shorter than the median time it took for erosions to appear, the 5.5% rate reflected only the earlier erosions (median follow up

time vs. time before erosion was shorter in three out of four groups: 6.5 vs. 15.6; 4.9 vs. 12.4; 6.1 vs. 9.0; 6.6 vs. 4.1 months):

> among the various vault suspensions. The overall mean follow-up time was 12.3 ± 16.7 months, and the median length of follow-up was 5.8 months (range, 1-87 months). The median length of follow-up was 6.5 months (range, 1-87 months) for abdominal sacral colpopexy, 4.9 months (range, 1-45 months) for abdominal sacral colpoperineopexy, 6.1 months (range, 1-28 months) for vaginally passed sutures, and 6.6 months (range, 2-11 months) for vaginally placed mesh. The median number of months to appearance of mesh erosion was 15.6 (range, 2-33 months) in the abdominal-only sacral colpopexy group, 12.4 months (range, 3-40 months) in the abdominal-only sacral colpoperineopexy group, 9.0 months (range, 5-15 months) in the suture-only group, and 4.1 months (range, 2-7 months) in the vaginal mesh group.

[47]

Considering that, statistically medians closely represent 50th percentile, the life-long rates would be expected more than to double with a sufficiently long follow up time. The authors acknkowledged that most erosions occur within two years after mesh implantation and some occur many years later:

> The time to vaginal mesh erosion seems to be quite variable with most erosions occurring within the first 2 years after surgery but some occurring many years later.

The study did not detect patient specific factors affecting the rates of mesh erosion:

The variables *age, weight, parity, estrogen status, concomitant hysterectomy,* and *posterior repair* were examined; however, none was found to be independently associated with mesh erosion. Because various types of permanent suture material were used to secure the mesh to the vagina, we divided the colpopexies into 2 groups—those that used monofilament suture and those that used braided suture. Mesh erosion was independent of type of suture used.

The authors considered mesh infection as one of the causes of erosions:

Mesh erosions may be the only clinical manifestation of a bacterial contamination. If this is true, it supports our

They also recognized that infection can be either primary or secondary event:

could explain this finding. By definition, the eroded mesh is directly exposed to the vagina; therefore it is difficult to know whether a positive culture of the mesh antedated the erosion or whether it was the result of post-erosion exposure of the mesh to the vaginal flora.

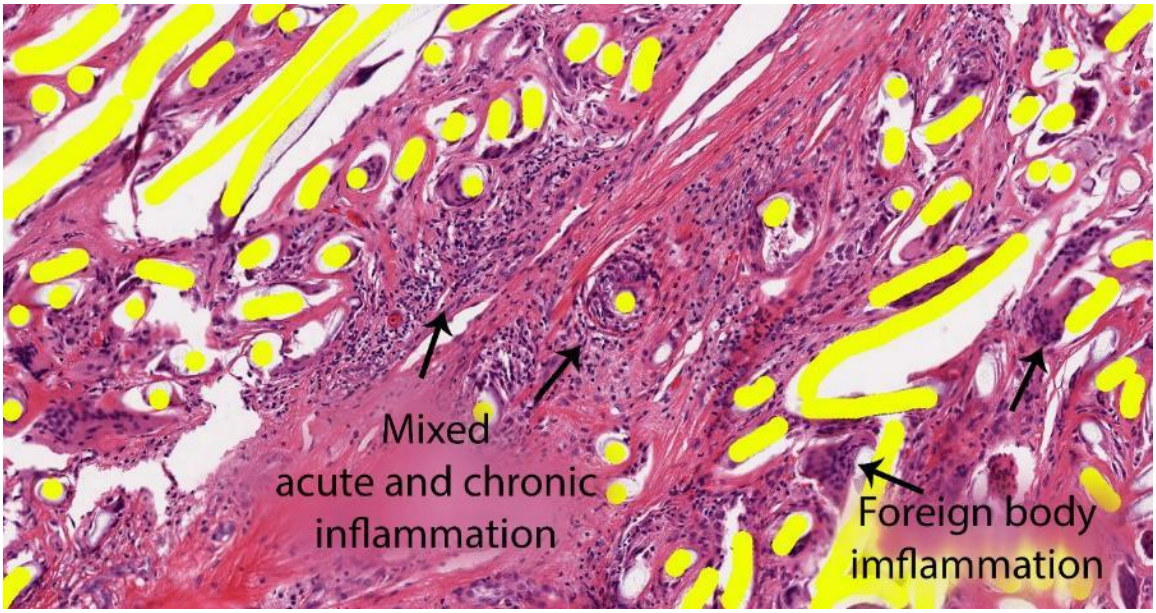
The final conclusion in the publication was that new materials are needed to lower the erosion rates:

ciple. In the future the development of other types of synthetic mesh, the use of biologic and potentially less reactive materials, or the combined use of these materials may provide reliable and strong support with fewer erosions.

[47]

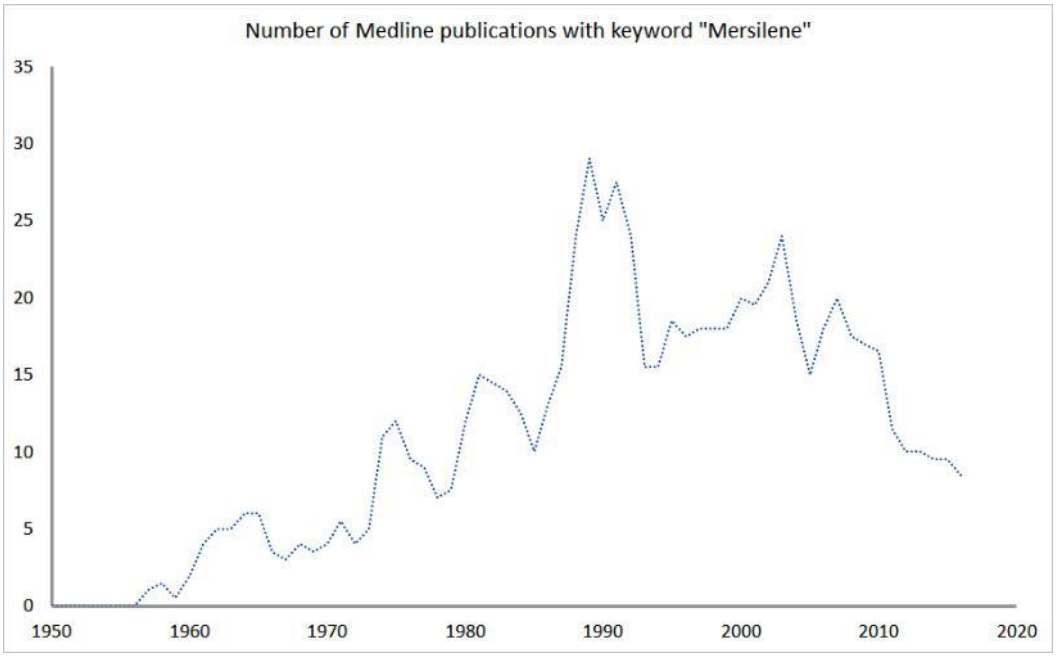
These conclusions were in line with the earlier studies and mesh classification based on the hernia surgical experience. The multifilament mesh design was determined to have higher risks of infection, and the risk was was design-specific.

For midurethral slings, multifilament polypropylene, not polyester meshes were attempted as a material for prefabricated devices. These devices have been used only for several years but the experience was sufficient to show that rates of infection and erosion were significantly higher than for the monofilaments designs. [48] [49] [50] [51] [52] [53] [2] [54] [55] [56] [57] [58] A number of reports described deep infection and subsequent formation of abscesses and more extensive tissue necrosis. [59] [60] [61] [62] [63] [64] [65] These devices left a strong trail of publications describing erosions and infections.



Infected multifilament polypropylene mesh. [36]

The above described experiences and knowledge affected use and introduction of new multifilament mesh designs. For example, in published literature, an annual number of publications with the keyword “Mersilene” listed on PubMed declined significantly since the 1990s.



The graph above was plotted using data generated by:

http://dan.corlan.net/medline-trend.html

I reserve the right to supplement this report if new information becomes available.

Vladimir Iakovlev, MD, FRCPC, FCAP DATE: June 23, 2018

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